

### **DETAILED ACTION**

Applicants' amendment filed 8/01/2011 is acknowledged.

The rejection of claims 32-46 under 35 U.S.C. 102(b) is withdrawn.

New ground of rejection is set forth as follows.

Claims 32 – 33 and 37-41 are being considered on the merits.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 32-33 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 5,468,727; hereinafter R1) in view of Tolle (US 6,706,294; of record; hereinafter R2).
3. R1 discloses a method of diagnosing and treating individuals with diabetes or risk to develop diabetes mellitus (Abstract). The method utilizes a substance that alters gastric emptying and is given in amount to delay gastric emptying so that normal rates are attained (col. 2, lines 60-66). R1 discloses that glucose metabolic indicators relate to metabolic events. Such parameters include blood glucose levels, blood insulin levels, post prandial glucose etc. One or more of these parameters may exceed normal range without indication to the individual that altered metabolic patterns are developing (col. 2, line 67 to col. 3, line 10). A pharmaceutical composition of a compound that delays

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gastric emptying and an oral hypoglycemic in an orally acceptable form is taken by the patients (col. 4, lines 57-65). The glucose level in diabetic and non-diabetic patients are compared (Fig. 4).

4. R1 does not specifically disclose blood sugar concentrations at fasting conditions or postprandial conditions, however, the blood sugar concentration at different conditions (i.e., fasting or postprandial) are well known in the art and are expected to be determined to clarify the status of individuals under consideration, especially, as disclosed by R1, that glucose metabolic indicators relate to metabolic event.

5. While R1 discloses a method for treating the individuals having altered metabolic patterns, R1 is silent regarding the administration of lactic fermented distiller's grains.

6. R2 discloses the full process of fermenting the distiller's grains with yogurt or butter cultures. The processing steps are disclosed as presently claimed in claim 38. (col. 1, lines 22-37).

7. R2 teaches of dosing quantities of 21-25 grams to be effective doses. R2 discloses that 135 g of the fermented mass having 17% dry matter would provide the required dose. R2 then teaches of mixing the effective dose with other foods including milk preparations that can be presented in portions of 200-250 g ready to consume units. (col. 1, lines 50-60).

8. R2 discloses that the fermentation with a yogurt culture or butter culture causes the residual sugars and carbohydrates to be metabolized into lactic acid so that the product contains even less sugars and carbohydrates and is thus more suitable for diabetics (col. 2, lines 4-12), for slimming cures, for recovery after operations, for

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dietetic foods, for the treatment of amino acid deficiency, for pancreatic functional disorders, carbohydrate addiction diseases, for intestinal functional disorders (col. 2, lines 55-61), for diabetics and weight reduction (col. 2, lines 47-48).

9. R2 discloses the inventive product can also be used as a supplementary diet during slimming cures (col. 2, lines 55-56). The consumption of the product as a food supplement is disclosed by R2 ( col. 3, lines 10-15)

10. Given that R2 discloses utilizing the fermented distiller's grains for the reduction of diabetic effects (i.e. reducing blood sugar level) and weight reduction, and noting that lactic fermented distiller's grains is a hypoglycemic material (i.e. due to depletion of fermentable sugars), it would be motivating to employ it in subjects with increased blood sugar level.

11. R2 also discloses the incorporation of the fermented product into food supplements. (Claims 9- 11).

12. In summary, R1 discloses a method for treating subjects who are either diabetic or at high risk for diabetes by first determining the glucose metabolic indicators, such as blood sugar, or postprandial glucose etc. The subjects are then treated by administering compounds orally; to alleviate such effect. R2 describes a process for producing lactic fermented distiller's grains; disclosing that such products are hypoglycemic, because of fermentations, and are useful for people of high blood sugar levels.

13. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to determine the blood glucose levels in individuals under investigation as disclosed by R1 to determine the metabolic status of individuals at risk,

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and treat the individuals at risk, with the lactic fermented distiller's grains as motivated by R2; expecting to observe a blood sugar lowering effect. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to implement the method as presently claimed.

### ***Response to Arguments***

In light of the new grounds of rejection, Applicants' arguments are moot.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/D. Lawrence Tarazano/  
Supervisory Patent Examiner, Art Unit 1781

Hamid R Badr  
Examiner  
Art Unit 1781